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IN THE

Supreme Court of the United States

DONNA S. RIEGEL, individually and as administrator of the estate of Charles R. Riegel,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF CROPLIFE AMERICA, AMERICAN CHEMISTRY COUNCIL, AND CONSUMER SPECIALTY PRODUCTS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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BRIEF OF CROPLIFE AMERICA, AMERICAN CHEMISTRY COUNCIL, AND CONSUMER SPECIALTY PRODUCTS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

INTEREST OF THE *AMICI CURIAE* [1]

Amici curiae CropLife America, American Chemistry Council, and Consumer Specialty Products

[1] The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission.

Association are submitting this brief because they have a substantial interest in the development, interpretation, and application of this Court's jurisprudence on federal preemption of state-law damages claims involving products whose safety is closely regulated by expert federal agencies such as the Food and Drug Administration (FDA) and the United States Environmental Protection Agency (EPA). *Amici* believe that consumer protection is significantly strengthened by preemption of any type of tort claim that is based on a state-law duty which diverges from, conflicts with, or otherwise undermines federal safety regulation, especially in areas such as product labeling and warnings, where nationally uniform regulation is critical to proper usage.

CropLife America is the national trade association for the plant science industry. Its member companies develop, produce, sell, and distribute virtually all of the agricultural crop protection pesticides and biotechnology products used by American farmers to provide consumers with safe, affordable, and abundant food and fiber. For more than sixty years CropLife America has been industry's leading voice on significant federal and state pesticide regulatory issues. One such issue is the deleterious impact of state-law failure-to-warn claims on the system of nationally uniform product labeling which Congress mandated through enactment of § 136v(b) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b). CropLife America has participated as *amicus curiae* in numerous appeals involving the scope of FIFRA preemption under § 136v(b), including *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), a case upon which petitioner and the *amici curiae* supporting her heavily rely.

The American Chemistry Council represents the leading companies engaged in the business of chemistry. A substantial number of the Council's members produce and distribute pesticides, including a wide variety of antimicrobial products, which like all pesticide products, are comprehensively regulated under FIFRA by EPA.

The Consumer Specialty Products Association represents the interests of companies which provide households, institutions, and industrial customers with products that help provide a cleaner and healthier environment. Those products include disinfectants and insecticides used in homes, hospitals, and restaurants.

SUMMARY OF ARGUMENT

1. Petitioner and her *amici curiae* are attempting to use this premarket approval ("PMA") medical device product liability case as a vehicle for mounting an all-out assault on the principle, firmly established by this Court's federal preemption precedents, that state-law damages claims can be encompassed by a federal regulatory statute's express prohibition against state-imposed requirements. Their anti-preemption policy arguments, which present a lopsided view of the benefits of product liability litigation, mistakenly assume that manufacturers are totally immunized from liability by express preemption confined to damages claims that are based on state-law duties which diverge from federal regulatory requirements regarding safety-related subjects such as product design or labeling. They also incorrectly assume that such express preemption—although limited in scope—deprives persons injured by defective

products of their sole means for obtaining compensation.

2. Petitioner's theory that *no* damages claim can be encompassed by a federal statute's preemption provision unless Congress has manifested an unequivocal intent to preempt *any and all* damages claims not only is illogical, but also contrary to the claim-by-claim framework for express preemption analysis mandated by this Court's precedents, such as *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). In reaffirming this claim-by-claim approach, which the Second Circuit followed here in applying § 360k(a) of the Food, Drug, and Cosmetic Act's Medical Device Amendments ("MDA"), 21 U.S.C. § 360k(a), the Court should make it clear that the substance and elements of a state-law cause of action, and not the name a plaintiff assigns to a particular claim, determines whether it falls within the scope of a federal statute's express preemption provision.

3. Consumer protection is enhanced, not undermined, by federal preemption of damages claims that would impose state-law duties which diverge from or otherwise conflict with federal regulatory requirements. This is especially true where a federal statute's goal is to achieve national uniformity of regulation regarding product design, labeling, or other safety-related subjects. Conflicting or differing jury verdicts, which indisputably have a regulatory effect on a product's manufacturer, can impede, impair, or destroy the national uniformity that Congress seeks to achieve under the auspices of expert and experienced federal agencies such as FDA and EPA.

4. In opposing preemption of state-law damages claims, petitioner and her *amici* rely too much on flawed dicta in the *Bates* majority opinion, which addresses the preemptive scope of § 136v(b) of FIFRA. In particular, the history of prior tort litigation is irrelevant to the plain meaning of a preemption provision such as § 136v(b) of FIFRA or § 360k(a) of the MDA. Tort claims that impose divergent state-law duties can seriously disrupt federal regulatory programs. And the majority's suggestion that product liability litigation is the only means for obtaining compensation seems oblivious to corporate social responsibility and product stewardship programs which voluntarily compensate consumers when and if post-market problems develop.

5. The Court should clarify that the inferential "parallel requirements" exclusion from express preemption discussed in *Bates* and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), should not be applied in a way which nullifies congressional intent to preempt state requirements that are different from or in addition to federal requirements. A broad exclusion which encompasses any general common-law duty that is consistent with any general federal statutory standard would provide plaintiffs and their attorneys with a virtually automatic route around express preemption. Instead, the exclusion should apply only if a claim is based on a specific state-law duty that seeks to enforce a specific federal regulatory requirement.

ARGUMENT

I. MANUFACTURERS ARE NOT IMMUNIZED FROM PRODUCT LIABILITY SUITS BY EXPRESS PREEMPTION OF DAMAGES CLAIMS THAT ARE PREMISED UPON STATE-LAW DUTIES WHICH DIVERGE FROM FEDERAL REQUIREMENTS

In its opinion below, the court of appeals took "care to explain that [it did] not hold that all state tort claims as to PMA-approved devices are preempted." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 106 (2d Cir. 2006). The lower court further indicated that "contrary to the dissent's fear that the decision . . . will deprive those who were injured by an unreasonably dangerous medical device of any remedy whatsoever . . . the scope of [the] decision is actually quite limited." *Id.* at 124 (internal quotation marks omitted). Nevertheless, petitioner's wide-ranging attack on federal preemption of state-law damages claims involving federally regulated products approaches that subject as if it were an all-or-nothing proposition. Her arguments against preemption are predicated upon the mistaken notion that either Congress manifestly intended to afford *total* immunity to manufacturers of allegedly defective, federally regulated products, thereby depriving consumers of all judicial recourse, or such manufacturers necessarily are subject to the full panoply of state-law causes of action for product liability regardless of the plain, broad language of a federal statute's preemption provision.

Relying upon this "total immunity" fallacy, petitioner asserts that the issue before the Court is whether a manufacturer such as Medtronic "is entitled to immunity from state-law damages suits,

regardless of their merits, the nature of Medtronic's conduct, or the severity of the resulting injuries." Pet. Br. at 14; *see also id.* at 1 (referring to "Medtronic's plea for immunity from liability"). Petitioner's *amici* follow the same tack.[2] Taking aim at this overblown target, petitioner argues that there is a "glaring absence in the legislative record of any suggestion that consumers would lose their only means of obtaining compensation for injuries." Pet. Br. at 19. She urges the Court to equate the lack of congressional intent to afford manufacturers blanket immunity from product liability suits with the opposite extreme, namely, that "Congress did not intend § 360k(a) to preempt damages claims at all." *Id.* at 15.

Petitioner's black-or-white approach to federal preemption of product liability litigation conflicts with the type of careful, claim-by-claim analysis which this Court repeatedly has indicated courts must follow when applying a federal regulatory statute's express preemption provision to damages suits. In analyzing the preemptive scope of § 5(b) of the Public Health Cigarette Smoking Act of 1969, which provides that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any

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[2] *See, e.g.*, Br. of AARP at 21 (arguing against "immunizing device manufacturers from tort suits"); Br. of Sen. Kennedy & Rep. Waxman at 8 ("Congress did not intend to preempt state tort suits."); Br. of Am. Ass'n for Justice at 8 ("The question before the Court is whether Congress intended [the MDA] to prevent future victims from bringing state-law tort actions . . . ."); Br. for the States of New York, *et al.* at 4-5 ("It is simply implausible that Congress . . . would have meant to supersede all of state tort law in the area of device safety.").

cigarettes," the Court in *Cipollone v. Liggett Group, Inc.*, explained why a claim-by-claim analysis is necessary:

> That the pre-emptive scope of § 5(b) cannot be limited to positive enactments *does not mean that that section pre-empts all common law claims*. . . . For purposes of § 5(b), the common-law is not of a piece.
>
> Instead . . . we must look to each of petitioner's common-law claims to determine whether it is in fact pre-empted.

505 U.S. at 523 (emphasis added). The Court then proceeded to consider whether § 5(b) of the Cigarette Act applied to each type of state-law damages claim alleged in the suit (e.g., failure to warn; breach of express warranty; fraudulent misrepresentation). *Id.* at 523-30; *see* Br. of Consumers Union at 3, 12 ("This Court's precedents on preemption dictate a close analysis of both the purportedly preemptive federal law and the purportedly preempted state rule. . . . a close reading of the [*Cipollone*] decision reveals the Court doing the work it has always done in pre-emption cases: assiduously comparing the allegedly preemptive federal statute with the specific state-law claims being pressed.").

The court of appeals adhered to this claim-by-claim analytical framework in applying § 360k(a) of the MDA to this case. First, the lower court, 451 F.3d at 114-16, discussed this Court's fragmented express preemption decision in *Medtronic, Inc. v. Lohr*, which in part V of the lead opinion analyzed the applicability of § 360k(a) to each of Medtronic's different types of claims, *see* 518 U.S. at 492-94 (discussing design claim) and *id.* at 497-502 (discussing manufacturing and labeling claims). The court then considered the

causes of action in this case, and concluded that some—but not all—tort claims involving PMA medical devices are expressly preempted by § 360k(a). *See Riegel*, 451 F.3d at 124 ("[T]ort claims that are premised on a manufacturer's deviation from the standards set forth in the device's approved PMA application . . . are in no way preempted. Only those claims that allege liability despite a PMA-approved device's adherence to those standards are . . . preempted.").

The Court should affirm the Second Circuit's holding, which concludes that § 360k(a) expressly preempts many types of state-law claims, *see id.* at 121, but neither immunizes medical device manufacturers from damages suits, nor deprives consumers of judicial recourse for non-preempted causes of action, *id.* at 123 (agreeing "with the district court's conclusion that the Riegels' negligent manufacturing claim was not preempted"). None of this Court's product liability preemption precedents, including *Bates v. Dow AgroSciences*, mandates or condones the wholesale approach to tort preemption that petitioner is advocating here (i.e., that *no* tort claims are preempted unless Congress deliberately and demonstrably intended to enact a provision that preempts *all* tort claims).

In *Bates*, a product liability suit involving a federally regulated pesticide, the Court reiterated its holding in both *Cipollone* and *Lohr* that an express preemption provision which prohibits states from imposing their own requirements "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties," 544 U.S. at 443, but that such a proscription does *not* afford manufacturers blanket immunity from product liabil-

ity suits. The Court indicated instead that to determine whether a particular claim is preempted, "[t]he proper inquiry calls for an examination of the elements of the common-law duty at issue." *Id.* at 445 (citing *Cipollone*, 505 U.S. at 524).

More specifically, *Bates* holds, based on the express terms of § 136v(b) of FIFRA, that "a particular state rule" is preempted only if it satisfies two conditions: "First, it must be a requirement *'for labeling or packaging*,'" and "[s]econd, it must impose a labeling or packaging requirement that is *'in addition to or different from* those required under [FIFRA].'" *Id.* at 444 (quoting 7 U.S.C. § 136v(b)).[3] Applying the first prong of this test for express preemption under FIFRA, the Court held that unlike "fraud and negligent failure-to-warn claims," which "are premised on common-law rules that qualify as 'requirements for labeling or packaging,'" *id.* at 446, "petitioners' claims for defective design, defective manufacture, negligent testing, and breach of express warranty are not preempted," *id.* at 444, because "[n]one of these common-law rules requires that manufacturers label or package their products in any particular way," *ibid.*

This Court's classification of different types of damages claims as falling either within or outside the scope of a statute's express preemption provision should not relieve a trial court of the task of analyzing each cause of action pleaded in a particular suit to determine whether it is preempted. For example,

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[3] Both the MDA and FIFRA contain "a similarly worded preemption provision." *Bates*, 544 U.S. at 447. Each preempts "any" state-imposed "requirements" that are "in addition to" or "different from" federal requirements. *Compare* 21 U.S.C. § 360k(a) and 7 U.S.C. § 136v(b).

prior to *Bates* numerous courts recognized that the applicability of § 136v(b) of FIFRA does not depend upon "the guise under which the claim is presented." *Netland v. Hess & Clark, Inc.*, 284 F.3d 895, 900 (8th Cir. 2002);[4] *see generally Aetna Health Inc. v. Davila*, 542 U.S. 200, 214 (2004) ("[D]istinguishing between pre-empted and non-pre-empted claims based on the particular label affixed to them would elevate form over substance and allow parties to evade the pre-emptive scope of [the statute] simply by relabeling their . . . claims." (internal quotation marks omitted); *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981) (preemption cannot be "avoided by mere artful pleading"). Along the same lines, Justice Thomas' separate opinion in *Bates*, joined by Justice Scalia, explains that "[a] state-law cause of action, *even if not specific to labeling*, nevertheless imposes a labeling requirement 'in addition to or different from' FIFRA's when it attaches liability to statements on the label that do not produce liability under FIFRA." *Bates*, 544 U.S.

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[4] *See, e.g., Nat'l Bank of Commerce v. Dow Chem. Co.*, 165 F.3d 602, 608 (8th Cir. 1999) ("It is immaterial whether an inadequate labeling or failure to warn claim is brought under a negligence or products liability theory."); *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 662 (7th Cir. 1997) (holding that § 136v(b) preempts claims for misrepresentation or express warranty based on oral or advertising statements "if they merely repeat information in the label itself"); *Grenier v. Vermont Log Bldgs., Inc.*, 96 F.3d 559, 565 (1st Cir. 1996) (holding that § 136v(b) preempts a purported design or manufacturing defect claim if it is actually a "disguised labeling claim"); *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366, 377 (Cal. 2000) ("When a claim, however couched, boils down to an assertion that a pesticide's label failed to warn of the damage plaintiff allegedly suffered, the claim is preempted by FIFRA.").

at 456 (emphasis added) (Thomas, J. concurring in the judgment in part and dissenting in part). But subsequent to the Court's seemingly rigid listing of non-preempted categories of claims in *Bates*, courts in pesticide-related suits have been acting reflexively, declining to look behind the name that a plaintiff assigns to a cause of action to determine whether it is based on a rule that qualifies as a requirement for labeling, and thus is preempted.[5] In affirming the Second Circuit's medical device preemption decision here, the Court should clarify *Bates*, and indeed emphasize that form does not trump substance when determining whether a state-law product liability claim, no matter how denominated, is expressly preempted by a federal regulatory statute such as the MDA or FIFRA.

II. CONSUMER PROTECTION IS ENHANCED BY EXPRESS PREEMPTION OF DAMAGES CLAIMS THAT ARE PREMISED UPON STATE-LAW DUTIES WHICH DIVERGE FROM FEDERAL REQUIREMENTS

Petitioner and her *amici* repeatedly assert that federal preemption of damages claims undermines

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[5] *See, e.g., Mortellite v. Novartis Crop Protection, Inc.*, 460 F.3d 483, 490 (3rd Cir. 2006) ("FIFRA does not preempt claims based on theories of strict liability, negligent testing, and breach of express warranty. As the Supreme Court explained, such common law claims plainly do not impose labeling requirements . . . ."); *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 887 (8th Cir. 2005) (rejecting, based on *Bates*, manufacturer's contention that plaintiffs' defective design and breach of warranty claims, "as pleaded," challenge the adequacy of FIFRA labeling requirements).

consumer protection. They contend that product liability litigation against manufacturers of federally regulated products is an essential and beneficial form of supplemental, state-by-state regulation necessitated by "constrained and conflicted" federal agencies. Br. of AARP at 6.[6] Further, they contend that preemption of damages claims "would improperly foreclose all remedies," Pet. Br. at 43, thereby depriving injured persons of their sole financial recourse.[7]

To the contrary, consumer protection is *enhanced* when highly experienced federal agencies, staffed by dedicated scientific experts, regulate products such as medical devices, drugs, and pesticides in a nationally uniform manner. Product liability claims based on state-law duties that diverge from or otherwise conflict with federal requirements can have a significant adverse impact on national uniformity of regulation concerning safety-related subjects such as product design and label warnings. Furthermore, the vast majority of manufacturers display a high degree

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[6] *See also* Br. of Am. Ass'n for Justice at 15 (referring to "the longstanding reliance on post-marketing liability as a complementary means to achieve product safety"); Br. of Consumers Union at 18 ("It has been, and should continue to be, the most unusual case when this Court upends the friendly collaboration between federal laws and state tort remedies."); Br. of AARP at 7 ("The limited PMA process . . . is entirely inadequate to replace the long-standing safety incentives and consumer protections provided by state tort law.").

[7] *See also* Pet. Br. at 19 (referring to the "absence in the legislative record of any suggestion that consumers would lose their only means of obtaining compensation for injuries caused by poorly designed or inadequately labeled PMA devices"); Br. of AARP at 27 ("Tort law provides the only relief for patients injured by defective medical devices.").

of corporate responsibility by voluntarily compensating consumers when and if safety-related problems develop with their products.

In proffering their objections to *any* federal preemption of damages claims, petitioner and her *amici* place too much reliance upon policy dicta included within Justice Stevens' majority opinion in *Bates*. As Justice Thomas, joined by Justice Scalia, indicated in his partial dissent,

> the majority [opinion] advances several arguments *designed to tip the scales in favor of the States* and against the Federal Government. These arguments, in addition to being *unnecessary*, are *unpersuasive*. . . . [O]ur task is to determine which state-law claims [the statute] pre-empts, without slanting the inquiry in favor of either the Federal Government or the States.

Bates, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part) (emphasis added).

1. The *Bates* majority opinion asserts that the "long history of tort litigation against manufacturers . . . adds force to the basic presumption against preemption." 544 U.S. at 449. Justice Thomas, joined by Justice Scalia, disagreed:

> The history of tort litigation against manufacturers is . . . *irrelevant*. . . . We cannot know, without looking to the text of § 136v(b), whether FIFRA preserved that tradition or displaced it. . . . [W]hile allowing additional state-law remedies likely aids in enforcing FIFRA's misbranding requirements . . . it is for Congress, not this Court, to strike a balance between state tort suits and federal regulation.

See id. at 457-58 (Thomas, J.) (emphasis added).[8] In the case of FIFRA, even if "tort litigation against pesticide manufacturers . . . was a common feature of the legal landscape at the time of the 1972 amendments," *id.* at 440-41, that ancient history is completely irrelevant. This is because "the extensive amendments" that Congress adopted in 1972, *id.* at 437, which were "spurred by growing environmental and safety concerns," *ibid.*, included "significantly strengthen[ing] FIFRA's . . . labeling standards," *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 601 (1991), in part by enacting § 136v(b). The purpose of § 136v(b) is to achieve and maintain national labeling uniformity by prohibiting states from imposing "requirements for labeling" that are "in addition to or different from" federal requirements. *See Bates*, 544 U.S. at 452.

Along the same lines, it is not surprising that a "groundswell of federal and state decisions" holding that certain types of tort claims are expressly preempted by a statutory prohibition against state-imposed "requirements," *Bates*, 544 U.S. at 441, did not emerge until after the Court's *Cipollone* opinion in 1992. Indeed, the Court triggered the wave of FIFRA tort preemption decisions when, within a week of deciding *Cipollone*, it vacated and remanded two FIFRA cases for further consideration in light of *Cipollone*. After both courts of appeals held on remand, based on *Cipollone*, that § 136v(b) expressly

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[8] Justices Thomas and Scalia have expressed the view that the presumption against preemption "does not apply . . . when Congress has included within a statute an express pre-emption provision." *Bates*, 544 U.S. at 457 (Thomas, J.) (citing *Cipollone*, 505 U.S. at 545-46) (Scalia, J., concurring in judgment in part and dissenting in part)).

preempts labeling-related damages claims, the Court declined further review,[9] and during the next twelve years denied certiorari in many other FIFRA preemption cases prior to granting review in *Bates*. Further, as the Court noted in *Bates*, 544 U.S. at 441, prior to *Cipollone*, only the D.C. Circuit had considered the question of whether damages claims are encompassed by § 136v(b), and contrary to this Court's subsequent holdings in *Cipollone*, *Lohr*, and *Bates*, held that the term "requirements" is limited to state positive enactments.[10]

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[9] *See Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 959 F.2d 158 (10th Cir.), *vacated and remanded*, 506 U.S. 910 (1992) (vacating and remanding for further consideration in light of *Cipollone*), *previous opinion adhered to*, 981 F.2d 1177 (10th Cir.), *cert. denied*, 510 U.S. 813 (1993); *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991), *vacated and remanded sub nom. Papas v. Zoecon Corp.*, 505 U.S. 1215 (1992) (vacating and remanding for further consideration in light of *Cipollone*), *aff'd sub nom. Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir.), *cert. denied*, 510 U.S. 913 (1993).

[10] The *Bates* majority opinion's invocation of that pre-*Cipollone* decision, *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984), is puzzling. *See Bates*, 544 U.S. at 451. In the wake of *Cipollone*, numerous courts of appeals and state appellate courts have held that *Ferebee* "is no longer good law." *Etcheverry v. Tri-Ag Serv.*, 993 P.2d at 372; *see, e.g., King v. E. I. DuPont de Nemours & Co.*, 996 F.2d 1346, 1351 (1st Cir. 1993) ("In deciding *Ferebee*, the District of Columbia Circuit did not have the benefit of the Supreme Court's subsequent analysis and ruling in *Cipollone* . . . we do not find *Ferebee* persuasive."). Moreover, the D.C. Circuit "has expressly acknowledged that *Cipollone* repudiated [*Ferebee*'s] central premise by 'explaining that damage actions . . . must be preempted where positive enactments are preempted.'" *Etcheverry*, 993 P.2d at 372 (quoting *Waterview Management Co. v. F.D.I.C.*, 105 F.3d 696, 699 (D.C. Cir. 1997)).

2. The *Bates* majority opinion denigrates the crucial role that national uniformity of regulation plays in promoting the safety of products such as medical devices, drugs, and pesticides. *See* 544 U.S. at 450 (asserting that the "United States greatly overstate[d] the degree of uniformity and centralization that characterizes FIFRA"). In the case of FIFRA, the fact that "the statute authorizes a relatively decentralized scheme that preserves a broad role for state regulation," *ibid.*, proves nothing about the statute's express preemption of divergent state *labeling* requirements. Congress mandated, through enactment of § 136v(b)—which is entitled "Uniformity"—that EPA establish and maintain a system of nationally uniform product labeling. To be sure, the statute preserves the states' supplemental role in regulating pesticide "sale or use." *See* 7 U.S.C. § 136v(a). But when Congress "transformed FIFRA . . . into a comprehensive regulatory statute," *Mortier*, 501 U.S. at 601 (internal quotation marks omitted), it did *not* "authorize[] a relatively decentralized scheme," *Bates*, 544 U.S. at 450, with regard to product labeling, which this Court acknowledges is "an area that FIFRA's [federal-state regulatory] 'program' pre-empts," *Mortier*, 501 U.S. at 615.[11]

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[11] Legislative materials demonstrate that when Congress enacted § 136v(b) in 1972 (four years prior to § 360k(a) of the MDA), it believed that EPA alone—and not the states—would have authority to regulate pesticide labeling. *See, e.g.*, H.R. Rep. No. 92-511 (1971) at 16 ("In dividing the responsibility between the States and the Federal Government for the management of an effective pesticide program, the [House] Committee [on Agriculture] has adopted language which is *intended to completely preempt State authority in regard to labeling.*") (emphasis added). Along the same lines, in *Mortier*, the Court explained that "FIFRA's historic focus [is] on labeling," 501 U.S.

Pesticide labeling is different from the ordinary labels placed on most types of non-federally regulated products. It enables EPA, a federal agency which possesses tremendous scientific expertise and decades of regulatory experience, to ensure that all necessary warnings, safety precautions, directions for use, and other essential information are communicated from a pesticide product's manufacturer through the chain of distribution to the individuals who actually use the product. The substantial health, safety, environmental, and product performance benefits that nationally uniform, EPA-regulated product labeling affords to consumers, farmers, and professional pesticide applicators cannot be overstated. The same undoubtedly is true for nationally uniform medical device and drug labeling.

The *Bates* majority opinion acknowledges the "narrow, but still important, role" that § 136v(b) plays in the FIFRA scheme: "In the main, it pre-empts competing state labeling standards—imagine 50 different labeling regimes prescribing the color, font size, and wording of warnings . . . ." 544 U.S. at 452. Further, the opinion holds that § 136v(b) expressly preempts "any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." *Ibid.* Yet, the opinion asserts that the United States, which appeared in *Bates* as *amicus curiae*, "exaggerate[d] the disruptive effects of using common-law suits to enforce the prohibition on misbranding," *id.* at 451.

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at 613, and that when Congress rewrote FIFRA in 1972, it "significantly strengthened" the Act's "labeling standards," *id.* at 601, in part by enacting § 136v(b).

To the contrary, where as in the case of the MDA or FIFRA, national uniformity with respect to a particular regulated subject such as labeling is an undeniable statutory objective, *especially* where that goal is expressed in a plainly and broadly worded preemption provision and is not constrained by a saving clause, damages claims that encroach upon the federal regulatory scheme necessarily conflict with congressional intent and threaten to destroy uniformity. Where "the pre-emption provision itself reflects a desire to subject the industry to a single, uniform set of federal safety standards . . . [t]his policy by itself favors pre-emption of state tort suits, for the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different decisions on similar facts." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 871 (2000).

In the same vein, petitioner concedes that § 360k(a) of the MDA was enacted to supplant state regulation and achieve nationwide uniformity, *see* Pet. Br. at 7, 16, but fails to reconcile that important, safety-related statutory objective with this Court's repeated holding that damages awards are a form of state regulation. *See, e.g., Cipollone*, 505 U.S. at 521. Even if, as petitioner asserts, "the impetus for Congress's enactment of a preemption provision [in the MDA] was the existence of state regulatory programs that potentially could subject device manufacturers to inconsistent requirements once federal requirements were put into place," Pet. Br. at 16, it would be illogical to assume that Congress would have wanted to allow the states to circumvent preemption and impose such inconsistent requirements through dam-

ages awards. *See Lohr*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment) (discussing the "anomalous consequences" of failing to recognize that "[t]he effects of the state agency regulation and the state tort suit are identical"). As the court of appeals explained below, in the absence of preemption "it is certainly conceivable that different juries would reach conflicting verdicts about the same medical devices, thus rendering it almost impossible for a device to comply simultaneously with its federal PMA (which, after all, can only change after an extensive process) and with the various verdicts issued by different juries around the country." *Riegel*, 451 F.3d at 122. This Court should affirm the opinion below "to avoid the conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety-standard cooks might otherwise create." *Geier*, 529 U.S. at 871.

3. The *Bates* majority opinion erroneously suggests that "depriv[ing] injured parties of a long available form of compensation," 544 U.S. at 449, would eliminate their only recourse. That proposition is necessarily incorrect where, as in the case of the MDA and FIFRA, an express preemption clause is limited in scope, and thus does not cloak a manufacturer with blanket immunity from product liability suits. Further, the premise that litigation is the only way to obtain compensation for defective products simply is not true. Most companies that market federally regulated products such as medical devices, drugs, and pesticides are responsible corporate citizens and seek to avoid litigation by voluntarily compensating persons legitimately claiming to have been injured by their products.

For example, as a matter of good product stewardship and sound business sense, agricultural pesticide manufacturers, through their regional and local representatives, work closely with individual farmers to investigate and resolve pesticide-related problems, such as crop injury. When circumstances warrant, manufacturers voluntarily provide a variety of remedies such as cost reimbursement, pesticide reapplication, replacement of seed, or monetary compensation. In the infrequent event of widespread problems, manufacturers establish formal claims resolution programs to try to learn more about the claims and avoid the costs and burdens of litigation for the benefit of all parties and the public.

III. THE "PARALLEL REQUIREMENTS" EXCLUSION SHOULD APPLY ONLY TO DAMAGES CLAIMS THAT ARE PREMISED UPON BREACH OF A SPECIFIC STATE-LAW DUTY TO COMPLY WITH A SPECIFIC FEDERAL REQUIREMENT

As an alternative to their contention that "Congress did not intend § 360k(a) to preempt damages claims at all," petitioner asserts "that, if § 360k(a) is nonetheless read to encompass damages claims, such preemption would occur only in very narrow circumstances." Pet. Br. at 15-16. Indeed, in part III of her brief, *id.* at 39, petitioner attempts to transform the "parallel" state requirements exclusion from preemption discussed in *Bates*, 544 U.S. at 447-48, and *Lohr*, 518 U.S. at 494-97, 513 (O'Connor, J., concurring in part and dissenting in part), into a *gaping loophole* which would swallow any preemption provision that prohibits states from imposing their own, additional or different regulatory requirements, either through positive enactments or damages awards. In affirm-

ing the opinion below, the Court should make it clear that the "parallel requirements" exclusion discussed in *Bates* and *Lohr* should not be applied in a way that renders express preemption provisions meaningless. *See generally* NORMAN J. SINGER, J.D. SHAMBIE SINGER, STATUTES AND STATUTORY CONSTRUCTION § 46.6 (7th ed. 2007) ("A statute should be construed so that effect is given to all of its provisions, so that no part will be inoperative or superfluous, void or insignificant . . . .").

In *Bates* the Court, finding "strong support" in *Lohr*, adopted a "'parallel requirements' reading of § 136v(b)" that excludes "a state-law labeling requirement . . . if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447. The Court indicated that "[s]tate-law requirements must also be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." *Id.* at 453; *see, e.g.*, 40 C.F.R. Part 156 (Labeling Requirements for Pesticides). Thus, the Court held that § 136v(b) "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations," but "[i]t does not . . . pre-empt any state rules that are fully consistent with federal requirements." *Id.* at 452. The Court stressed that although "the state-law requirement need not be phrased in the *identical* language as its corresponding FIFRA requirement . . . If a case proceeds to trial, the court's jury instructions must ensure that nominally equivalent labeling requirements are *genuinely* equivalent." *Id.* at 454.

Seizing upon the "parallel requirements" language in *Bates* and *Lohr*, petitioner contends that "the

Riegels' claims are not preempted for the additional reason that they are based on duties that mirror federal design and labeling requirements." Pet. Br. at 39. Petitioner contends that all it takes to avoid an otherwise broadly stated express preemption provision (e.g., a preemption provision prohibiting states from imposing requirements that are different from or in addition to federal requirements) is a state-law claim that is based on a *general* common-law duty (e.g., the duty to provide adequate warnings) and a similarly general federal statutory standard or requirement (e.g., the duty to distribute a product that is not misbranded). *See id.* at 42.[12] According to petitioner, "[s]tate damages claims are ordinarily premised on duties of general applicability, such as the duty to warn of risks or to use due care in the design of a product," *id.* at 38, and such common-law duties escape preemption because they are "equivalent to the federal standards." *Id.* at 14.[13]

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[12] Like petitioner, some trial courts have read *Bates* as requiring only the most superficial type of comparison to conclude that a state-law failure-to-warn or fraud claim, although premised on state-law requirements for labeling, falls outside the scope of § 136v(b) of FIFRA. *See, e.g., Booth v. Bd. of Regents*, No. Civ.A. 7:05-CV-34, 2005 WL 2099246, at *3 (M.D. Ga. Aug. 30, 2005) ("In this case, the requirements that would be imposed by the Georgia law of fraud are consistent with FIFRA."); *Central Valley Fresh Produce, Inc. v. Wilbur-Ellis Co.*, No. 04 CE CG 00542 (Cal. Super. Ct., Fresno Cty. June 30, 2005) ("[H]ere plaintiff's claims of inadequate warnings or instructions on the product label appear to be consistent with FIFRA's misbranding provisions, since the statute expressly forbids false or misleading statements on a product as well as inadequate instructions or warnings.").

[13] Damages claims based on general common-law duties purporting to be applicable to federally regulated medical devices

For example, petitioner asserts that any medical device-related inadequate warning claim arising under New York law falls outside the scope of § 360k(a) of the MDA because "[t]he generally applicable New York state-law duty to warn mirrors [the] general federal requirement" prohibiting the marketing of a "misbranded" medical device. *Id.* at 42. Similarly, petitioner argues that because New York law relating to the duty to design reasonably safe products "states these obligations very generally . . . a state determination, through a damages verdict, that a device was not reasonably safe is consistent with the federal scheme." *Id.* at 40.

To be sure, this Court held in *Lohr* and *Bates* that even a broad federal statutory prohibition against states imposing their own, "different" or "additional" requirements through damages claims does not encompass identical, parallel, equivalent, or fully consistent state requirements. In *Bates* the Court left it to the court of appeals to determine, on remand, whether the "particular common-law duties" underlying the petitioners' fraud and failure-to-warn claims "are equivalent to FIFRA's misbranding standards," 544 U.S. at 447, "emphasiz[ing] that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive preemption," *id.* at 453.

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should not be confused with FDA's regulatory exemption from preemption for state "requirements of general applicability where the purpose of the requirement relates . . . to *other products* in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code . . .)." 21 C.F.R. § 808.1(d)(1) (emphasis added).

According to petitioner's expansive view of the parallel requirements exclusion, however, virtually every product liability claim involving a federally regulated product is based on a general common-law duty that is equivalent to a general federal statutory standard, and therefore, no product liability claim ever would impose a state-law requirement that is "different from" or "in addition to" a federal regulatory requirement, and thus, be expressly preempted. If such a facile comparison of general common-law tort duties (e.g., the duty to warn) with general federal statutory requirements (e.g., the requirement to ensure that products are not misbranded) were sufficient to save damages claims from preemption, the congressional allocation of regulatory authority between the Federal Government and the states reflected in the terms of an express preemption provision such as § 360k(a) of the MDA or § 136v(b) of FIFRA would be rendered meaningless. *Cf. United States v. Locke*, 529 U.S. 89, 106 (2000) ("We decline to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law.").

The Court, therefore, should reject petitioner's wholesale attempt to circumvent express preemption of damages claims by means of the parallel requirements exclusion. Instead, to give meaning to *both* express preemption of additional or different state requirements and the implicit exclusion for parallel requirements, the Court should clarify *Lohr* and *Bates* by holding that the exclusion applies only to damages claims premised upon a manufacturer's alleged breach of a state-law duty to comply with a *specific federal requirement*. "While States are free to impose liability predicated on a *violation of the*

federal standards set forth in FIFRA and in any accompanying regulations . . . they may not impose liability for labeling requirements predicated on *distinct state standards* of care." *Bates*, 544 U.S. at 455 (Thomas, J., concurring the judgment in part and dissenting in part) (emphasis added).

For example, in holding that § 360k(a) does not preempt petitioner's defective manufacturing claim, the court of appeals indicated that "[a] jury verdict in the Riegels' favor on this claim would not have imposed state requirements that differed from, or added to, the *PMA-approved standards* for this device, but would instead have simply sought recovery for Medtronic's alleged deviation from those standards." *Riegel*, 451 F.3d at 123 (emphasis added). Or, in the FIFRA context, a state-law claim alleging that a pesticide manufacturer failed to include on product labeling a *specific* warning that was *required by EPA* would be based on a state-law duty that is "*genuinely* equivalent" to the federal requirement, *Bates*, 544 U.S. at 454; *see also id.* at 442 ("Nothing in the text of FIFRA would prevent a State from making the violation of a *federal* labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law.") (emphasis added).[14]

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[14] Further, because a pesticide label containing all warnings required under FIFRA would not be misbranded for lack of adequate warnings, *see* 7 U.S.C. § 136(q)(1)(G), a failure-to-warn claim concerning that pesticide necessarily would impose state-law requirements for labeling that are in addition to or different from the federal requirements, and therefore, would be expressly preempted. *See Bates*, 544 U.S. at 454 ("For a manufacturer should not be held liable under a state labeling require-

But a damages claim premised upon noncompliance with a specific state-law duty that parallels a specific federal requirement (such as a federal design or labeling specification) is quite unlike a product liability claim premised upon breach of a general common-law duty to design reasonably safe products or to provide adequate labeling and warnings. The "liability-creating premise" for the latter type of claim "is that the [product] itself, in its present [federally] approved form, is in some way defective and therefore requires modification." *Riegel*, 451 F.3d at 122. This type of claim should not be allowed to automatically escape a federal regulatory statute's express preemption of additional or different, state-imposed requirements merely because it is based on a general state-law duty that is consistent with a general federal regulatory standard or requirement.

Thus, a damages claim premised upon failure to design a medical device in a way that differs from the device's FDA-approved design, including any specific FDA design requirements, would be preempted by § 360k(a) even though the general common-law duty to design reasonably safe products is consistent with the general MDA requirement that the safety and effectiveness of the device be reasonably assured. *Cf. Lohr*, 518 U.S. at 503-04 (Breyer, J., concurring in part and concurring in the judgment) (discussing, by way of example, why a claim based on failure to design a hearing aid component with a 1-inch wire would be preempted if FDA regulations require a 2-inch wire). Similarly, a claim based on a manufacturer's failure to provide pesticide label warnings

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ment subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA.").

that go beyond those required by EPA would be based on a "common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations," *Bates*, 544 U.S. at 452, and would be expressly preempted by § 136v(b) even though the state common-law duty to provide adequate warnings is consistent with FIFRA's prohibition against misbranding.[15]

The vast majority of manufacturers go to great lengths to ensure compliance with all requirements pertaining to the design, safety, labeling, and sale of their federally regulated products. While the parallel requirements exclusion would enable a damages claim to avoid preemption in the event of a manufacturer's noncompliance with specific federal design, labeling, or other requirements, this Court should not allow it to function as a readily accessible means for flouting congressional intent.

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[15] In one of the leading pre-*Bates* cases on FIFRA preemption, *Worm v. American Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993), the court of appeals held that § 136v(b) permits "a state . . . to recognize that a breach of a *FIFRA-created duty* forms the basis for a state remedy," but that "[a]llowing such actions . . . is substantially distinguishable from accepting the argument that the state common law duty to warn is not 'in addition to or different from' the federally defined duty." *Id.* at 748 (emphasis added).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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